

REMARKS

This Application has been carefully reviewed in light of the *Office Action*. At the time of the *Office Action*, Claims 40-44, 46-57, 62, 63, and 67-70 were pending, of which, the Examiner rejected Claims 40-44, 46-57, 62, 63, and 67-70. Applicants have amended Claims 40-41, 55-56, 67, and 70 and left Claims 42-44, 46-54, 57, 62-63, 65-66, and 68-69 unamended. Applicants respectfully request reconsideration and favorable action in this case.

Objections to the Specification

The Examiner objects to the Specification under 35 U.S.C. §132(a) because the Specification allegedly does not provide support for the term “substantially” constant as used in conjunction with various physical characteristics of Applicants’ device (e.g., thread height and thread pitch). However, the Examiner admits that the specification supports a constant thread height and thread pitch. Applicants respectfully traverse this objection.

According to the M.P.E.P., “[b]y disclosing in a patent application a device that inherently . . . has a property . . . a patent application necessarily discloses that function, theory or advantage, even though it says nothing explicit concerning it. The application may later be amended to recite the function, theory or advantage without introducing prohibited new matter.” §2173.07(a).

Applicants respectfully contend one of ordinary skill in the art would appreciate Applicant’s specification supports substantially constant physical characteristics (e.g., thread pitch and the thread height) for example due to manufacturing imperfections or tolerances.

Objections to the Drawings

The Examiner objects to the Drawings because, according to the Examiner, new FIGURE 4 appears to be too different than FIGURE 1. See *Office Action*, page 4, lines 1-4. Applicant respectfully disagree with this rejection.

According to the M.P.E.P., “information contained in any one of the **specification**, **claims**, or **drawings** of the application as filed may be added to **any other part** of the application without introducing new matter.” See § 2163.06. According to this standard, FIGURE 4 does not add new matter. As the Examiner admitted on page 3 lines 17-19 of the *Office Action*, “applicant appears to have support for constant thread height and pitch.”

Accordingly, Applicants respectfully contend that no new matter has been added by FIGURE 4 and respectfully request that the Examiner withdraw the objection to FIGURE 4.

Section 112 Rejections of Claims 40, 44, 46, 48, 55-57, 62-63 and 65-70

The Examiner rejects Claims 40, 44, 46, 48, 55-57, 62-63 and 65-70 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner further rejects Claims 41-43, 45-54, 56-57, 62-63, and 65-70 under 35 U.S.C. § 112, second paragraph as being indefinite. Applicants respectfully traverse these rejections for the reasons stated below.

With respect to Claims 40, 44, 46, 48, 55, 67, and 70, the Examiner contends that “applicant does not have support for the term ‘substantially’ which broadens the dimensions to a range such that adjacent threads may have slightly different dimensions.” See *Office Action*, page 5, lines 1-5. In response, Applicants respectfully direct the Examiner’s attention to Applicants’ remarks regarding the Examiner’s objection to the Specification and contend that, for similar reasons, the Specification supports the limitations of Claims 40, 44, 46, 48, 55, 67, and 70. Consequently, Applicants respectfully request the Examiner to withdraw the associated rejections of Claims 40, 44, 46, 48, 55, 67, and 70 under 35 U.S.C. § 112, first paragraph.

With respect to Claims 40, 55, 67, and 70 and various of their respective dependent claims (Claims 56-57, 62-63, 65-66, and 68-69), the Examiner contends that the limitation “‘configured to *fit precisely* into a sinus tarsi’ is considered new matter.” See *Office Action*, page 5, lines 6-10. To advance prosecution, Applicants have amended Claims 40, 55, 67, and 70 such that each of said claims includes limitations generally directed to a body that is configured to fit snugly in into a sinus tarsi. Consequently, Applicants respectfully request the Examiner to withdraw the associated rejections of Claims 40, 55-57, 62-62, and 65-70 under 35 U.S.C. § 112, first paragraph.

With respect to Claim 41-43 and 46-54, the Examiner contends that Claim 41 has improper dependency. See *Office Action*, page 5, lines 17-18. In response, Applicants have amended Claim 41 to depend from Claim 40. Consequently, Applicants respectfully request the Examiner to withdraw the associated rejections of Claim 41-43 and 46-54 under 35 U.S.C. § 112, second paragraph.

With respect to Claims 41, 56, 67, and 70 and various of their respective dependent claims (Claims 42-43, 46-54, 57, 62-66, and 68-69), the Examiner contends that the limitations, “the leading flank separated by [sic] the trailing flank by a thread angle” is indefinite and unclear. See *Office Action*, page 5, lines 19-20. To advance prosecution, Applicants have amended Claims 41, 56, 67, and 70 to clarify that the leading flank and the trailing flank define a thread angle. Consequently, Applicants respectfully request the Examiner to withdraw the associated rejections of Claim 41-43 and 46-54, 56-57, and 62-70 under 35 U.S.C. § 112, second paragraph.

Section 102 Rejections

The Examiner rejects Claims 40, 41, 52, 53, 55, 56, 62, and 66 under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,607,304 (“*Bailey*”). The Examiner further rejects Claims 40, 41, 47, 50, 52-56, 62, 63, 66, and 70 under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,683,460 to Persoons (“*Persoons*”). Applicants respectfully traverse these rejections for the reasons stated below.

I. Neither *Bailey* nor *Persoons* disclose a body configured to fit snugly into a sinus tarsi as generally required by Claims 40, 55, and 70.

Applicants respectfully submit that both *Bailey* and *Persoons* fail to disclose, or even teach or suggest, the elements specifically recited in Applicants’ claims. For example, *Bailey* and *Persoons* fail to disclose, teach, or suggest the following elements recited in independent Claim 40:

A medical implant, comprising:

a body **configured to fit snugly** into a sinus tarsi of a subtalar joint in a human foot,

To reject these limitations, the Examiner does not point to any support in either *Bailey* or *Persoons*, but rather conclusorily states (1) that *Bailey*’s alleged medical implant is “capable of placement at such location to fit between bones” and (2) that *Persoons*’ medical implant is “capable of placement at such location and capable of such a fit as Persoon’s [sic] device is relatively small and intended for use between bones to act as a spacer.” See *Office Action* page 6, line 12, page 7, line 4. Applicants respectfully disagree with these rejections.

With regard to *Bailey*, the Examiner identifies a shaft portion of “abutment 16” as the body of Claim 1. *Office Action* page 6, line 11. With regard to *Persoons*, the Examiner identifies a “body 102” as the body of Claim 1. *Office Action* page 7, line 3. In general, Applicants do not necessarily agree with the Examiner’s identifications but refer to them for the sake of argument. Respectfully, nothing in the entirety of either *Bailey* or *Persoons* discloses that the alleged bodies described therein are “configured to fit **snugly** into a sinus tarsi” as required by Claim 40. Moreover, the Examiner’s argument that the alleged bodies of *Bailey* and *Persoons* are “capable of” fitting in a sinus tarsi does not address the requirements of a snug fit.

Consequently, at a minimum, both *Bailey* and *Persoons* fail to disclose, teach, or suggest “a body **configured to fit snugly** into a sinus tarsi” of independent Claim 40. For at least these reasons, Applicants respectfully request the Examiner to withdraw the rejection of independent Claim 40 and its dependent claims under 35 U.S.C. § 102. For analogous reasons, independent Claims 55, and 70 and their respective dependent claims are allowable under 35 U.S.C. § 102. Furthermore, Applicants contend that the above-presented arguments apply with equal force to distinguish these claims from further rejections under 35 U.S.C. § 103 presented by the Examiner below based on the same art.

II. Neither Bailey nor Persoons disclose a thread configured to reduce or eliminate pain as generally required by Claim 52.

Applicants further contend that neither *Persoons* nor *Bailey* disclose, or even teach or suggest, the following elements recited in Claim 52:

the thread is configured to secure the body into the sinus tarsi, and to **reduce or eliminate pain** caused to a patient by the thread once the medical implant is inserted into the sinus tarsi

In the *Office Action*, the Examiner did not address these limitations. Applicants respectfully remind the Examiner, “[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” M.P.E.P. § 2131 (citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)). For these additional reasons, Applicants respectfully contend that Claim 52 is allowable under 35 U.S.C. § 102.

III. Persoons does not disclose a leading flank or a trailing flank as required by Claims 41, 56, and 70.

Applicants further contend that *Persoons* does not disclose, or even teach or suggest, the following elements recited in Claim 41:

the thread includes a leading flank **inclined away from the second end** and spanning from the crest to a thread root and a trailing flank **inclined away from the first end** and spanning from the crest to the thread root, the leading flank and the trailing flank defining a thread angle.

The Examiner relies on the passage of *Persoons* at Col. 3, lines 23-25 to teach these elements. According to the passage:

Body 2 bears a blocking member in the form of a helical thread 5 protruding radially from body 2. Thread 5 has a non-cutting, blunt or flat edge. The **head 3 is separated from the collar 7 by a steep edge** while the generating line of the helical thread 5 is substantially perpendicular to the longitudinal axis of the body 2.

That is, the passage discloses that a “steep edge” separates head 3 from collar 7. Applicants respectfully point out that this statement does not involve the alleged thread of *Persoons* but rather the separation between head 3 and collar 7. In fact, nothing in *Persoons* a thread that includes leading flank **inclined away from the second end** a trailing flank **inclined away from the first end**. For these additional reasons, Applicants further respectfully request the Examiner to withdraw the rejection of Claim 41 and its dependent claims based upon *Persoons* under 35 U.S.C. § 102. For analogous reasons, Applicants respectfully request the Examiner to withdraw the rejections of Claims 56, and 70 and their respective dependent claims with respect to *Persoons* under 35 U.S.C. § 102.

Section 103 Rejections

The Examiner rejects Claims 43, 46, 48, 49, 50, 51, and 65 under 35 U.S.C. § 103(a) as allegedly being unpatentable over *Bailey*. The Examiner rejects Claims 40, 41, 43, 50, 52, 53, 55, 56, 62, and 66 under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 5,961,524 to Crombie (“*Crombie*”). The Examiner rejects Claims 42, 44, and 57 under 35 U.S.C. § 103(a) as allegedly being unpatentable over *Persoons* in view of U.S.

Patent No. 5,951,560 to Simon et al. ("*Simon*"). The Examiner rejects Claims 67-70 under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Publication No. 2004/0097928 A1 by Zdeblick et al. ("*Zdeblick*") in view of U.S. Patent No. 5,897,593 to Kohrs et al. ("*Kohrs*"). Applicants respectfully traverse these rejections for the reasons stated below.

IV. Crombie does not disclose, teach, or suggest "a body configured to fit snugly into a sinus tarsi" as generally required by Claims 40 and 55.

As mentioned above, Claim 40 is directed, in part, to a medical implant having "a body configured to fit **snugly** into a sinus tarsi of a subtalar joint in a human foot." To reject these limitations, the Examiner does not point to any support in *Crombie*, but rather identifies an "entire screw 10" as the body of Claim 40 and conclusorily states that *Crombie's* screw 10 is "capable of placement at such a location and due to its disclosed wide variation of shape/size, it is capable of precise fit." Applicants respectfully disagree with this rejection.

Applicants respectfully point out that the Examiner is arguing that the entire screw 10 of *Crombie* (including a head) is configured to fit into a sinus tarsi of a human foot. The entire screw 10 of *Crombie* is **not** configured to fit snugly into a sinus tarsi at least because screw 10 includes a screw head that would cause an uncomfortable pressure point in the sinus tarsi. For example, Applicant's specification states that localized pressure points between the implant and the surrounding bones may cause pain or even result in the implant popping out of the sinus tarsi. See Specification, page 9.

Consequently, at a minimum, *Crombie* fails to disclose, teach, or suggest "a body configured to fit **snugly** into a sinus tarsi" of Claim 40. Thus, combination of *Crombie* with the knowledge of one of ordinary skill in the art as proposed by the Examiner fails to disclose, teach, or suggest the elements of independent Claim 40. For at least these reasons, independent Claim 40 and its dependent claims are allowable under 35 U.S.C. § 103. For analogous reasons, independent Claims 55 and its respective dependent claims are allowable under 35 U.S.C. § 103.

V. Persoons does not disclose, teach, or suggest "a body adapted for implantation into a sinus tarsi" as generally required by Claims 44 and 55.

Applicants further contend that Persoons does not disclose, or even teach or suggest, the following elements recited in Claim 44:

a body **adapted for implantation into a sinus tarsi** of a subtalar joint in a human foot;

To reject these limitations, the Examiner does not cite to a passage of *Persoons* but rather states “*Persoon’s* [sic] discloses a medical implant and method of forming a medical implant substantially as claimed.” See Office Action, page 9, lines 12-13. Applicants respectfully disagree. According to *Persoons*:

The present invention relates to an intrafocal peg for stabilization and osteosynthesis of a **fracture in the wrist**.

See *Persoons*, Col. 1, lines 6-7. Consequently, at a minimum, *Persoons* fails to disclose, teach, or suggest “a body **adapted for implantation into a sinus tarsi** of a subtalar joint in a human foot” of Claim 44. Thus, combination of *Persoons* and *Simon* proposed by the Examiner fails to disclose, teach, or suggest the elements of independent Claim 44. For at least these reasons, independent Claim 44 and its dependent claims are allowable under 35 U.S.C. § 103.

VI. Neither Zdeblick nor Kohrs disclose, teach, or suggest a thread configured to reduce or eliminate pain as generally required by Claim 67.

Applicants further contend that *Persoon’s* does not disclose, or even teach or suggest, the following elements recited in Claim 67:

the thread is configured to secure the body into the sinus tarsi, and to **reduce or eliminate pain** caused to a patient by the thread once the body is inserted into the sinus tarsi

As discussed with respect to Claim 52 above, the Examiner did not address these limitations in the *Office Action*. Applicants respectfully remind the Examiner that “[a]ll words in a claim must be considered in judging the patentability of that claim against the prior art.” *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). Accordingly, Applicants respectfully contend that neither *Zdeblick* nor *Kohrs* disclose, teach, or suggest these limitations. For at least these reasons, independent Claim 67 and its dependent claims are allowable under 35 U.S.C. § 103. For analogous reasons, independent Claims 70 is allowable under 35 U.S.C. § 103.

Piecemeal Examination

Applicants note that the Examiner rejected the pending claims under 6 references. “The Examiner ordinarily should reject each claim on all valid grounds available, avoiding, however, undue multiplication of references.” M.P.E.P. 707.07(g). Applicants respectfully request that the Examiner limit such rejections to the best available art in order to not unduly burden Applicants in responding to any such rejection.

No Waiver

Applicants have merely discussed example distinctions from the references cited by the Examiner. Other distinctions may exist, and Applicants reserve the right to discuss these additional distinctions in a later Response or on Appeal, if appropriate. By not responding to additional statements made by the Examiner, Applicants do not acquiesce to the Examiner’s additional statements. The example distinctions discussed by Applicants are sufficient to overcome the Examiner’s rejections.

All claims are in condition for allowance

For at least the reasons explained above, Applicants respectfully contend that each and every one of the claims of the instance Application are in condition for allowance.

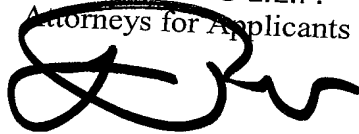
CONCLUSION

Applicants have made an earnest attempt to place this case in condition for allowance. For the foregoing reasons, and for other apparent reasons, Applicants respectfully request full allowance of all pending Claims. If the Examiner feels that a telephone conference or an interview would advance prosecution of this Application in any manner, the undersigned attorney for Applicants stands ready to conduct such a conference at the convenience of the Examiner.

Applicant believes no fee is due. However, if a fee is required, the Commissioner is hereby authorized to charge any fees or credit any overpayments to Deposit Account No. 02-0384 of Baker Botts L.L.P.

Respectfully submitted,

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